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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,725	08/06/2003	Stuart Neil Prince	1324030A	8868
23405	7590	10/19/2005	EXAMINER	
HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,725	<b>Applicant(s)</b> PRINCE ET AL.	
	<b>Examiner</b> Vanessa L. Ford	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **FINAL ACTION**

1. This Office Action is responsive to Applicant's amendment and response filed July 27, 2005. Claim 1 has been amended.
2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

### ***Rejection Withdrawn***

3. In view of Applicant's response the following rejections are withdrawn:
  - a) rejection under 35 U.S.C. 112, second paragraph, page 2, paragraph 2.
  - b) rejection under 35 U.S.C. 102(b), pages 4-5, paragraph 4.
  - c) rejection under 35 U.S.C. 102/103, pages 6-7, paragraph 6.

It should be noted that non-pathogenic is defined as not bringing disease into being as evidenced by MedicineNet.com. The Examiner is interpreting the term to broadly encompass its art recognized meaning since this term is not defined in the instant specification.

### ***Rejections Maintained***

4. The rejection of claims 1 and 7-16 under 35 U.S.C. 102(b) is maintained for the reasons set forth on pages 3-4, paragraph 3 of the previous Office Action.

The rejection was on the grounds Oldroyd et al teach that honeybee colonies were treated with various oxytetracycline hydrochloride (OTC) preparations at the same time of inoculation with *Bacillus larvae* spores. Oldroyd et al teach that colonies were inoculated with a comb (apicultural delivery vehicle) containing larvae sprayed with 20 ml of *Bacillus larvae* (page 692). Claim limitations such as "the composition of claim 1, wherein the inoculum comprises one or more microorganisms that produce one or more

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antibiotics active against one or more bee pathogens", "the composition of claim 7, wherein the antibiotics are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae subsp. larvae*", "the composition of claim 7, wherein the antibiotics are bacteriolytic" and the composition of claim 7, wherein the antibiotics are the anti-*Melissococcus pluton* and/or the anti-*Paenibacillus larvae subsp. larvae* antibiotics found in *Paenibacillus larvae subsp. pulvifaciens* would be inherent in the teachings of the prior art. The composition of Oldroyd et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that independent claims have been amended to recite a composition that comprise microorganisms that are non-pathogenic to bees. Applicant urges that Oldroyd et al teach a study of the effect of oxytetracycline hydrochloride on American Foulbrood. Applicant urges that Oldroyd et al indicate that the *Bacillus larvae* was cultured from adult bee samples from colonies that did not develop disease signs. Applicant urges that Oldroyd et al do not suggest that these colonies were disease free subsequently develop disease signs.

Applicant's arguments filed July 27, 2005 have been fully considered but they are not persuasive. Oldroyd et al teach a composition comprising *Bacillus larvae* that were American Foulbrood (AFB) disease-free at the time of sampling and did not subsequently develop disease signs (page 691). Therefore, the composition of the prior art teaches the claimed invention. Applicant has provided no side-by-side comparison to show that the claimed product differs from that of the prior art. Therefore, the teachings of Oldroyd et al anticipate the claimed invention.

5. The rejection of claims 1-16 under 35 U.S.C. 102/103 is maintained for the reasons set forth on pages 6-7, paragraph 6 of the previous Office Action.

Hoopingarner et al teach that bee colonies were sprayed with syrup containing *Bacillus larvae* spores (page 120). Hooperingarner et al teach that the colonies were treated with Terramycin (oxytetracycline hydrochloride) mixed in syrup, sprays, extender patties or sugar dust (page 120).

Hooperingarner et al do not specifically disclose a composition comprising a *Bacillus larvae* inoculum and an apicultural delivery vehicle that is a patty or a dusting or a paste or a spray. However, Hooperingarner et al disclose that compositions for the treatment of American foulbrood can be delivered using apicultural delivery vehicles such as a patty, a dusting, a spray or a paste.

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a suitable apicultural delivery vehicle to deliver the composition comprising *Bacillus larvae* for the treatment or prophylaxis of a bee disease because Hooperingarner et al have demonstrated that compositions for the treatment of American foulbrood can be delivered using apicultural delivery vehicles such as a patty, a dusting, a spray or a paste.

Applicant urges that independent claims have been amended to recite a composition the comprise microorganisms that are non-pathogenic to bees. Applicant there is no teaching in Hoopingarner et al of a composition comprising an inoculum of a non-pathogenic microorganisms for the prevention of *B. larvae* induced foulbrood disease.

Applicant's arguments filed July 27, 2005 have been fully considered but they are not persuasive. Hoopingarner et al teach a composition comprising disease resistant *Bacillus larvae* (120). Therefore, the composition of the prior art teaches the claimed invention. Applicant has provided no side-by-side comparison to show that the claimed product differs from that of the prior art. Therefore, the teachings of Hoopingarner et al anticipate the claimed invention.

***Status of Claims***

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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**Conclusion**

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vanessa L. Ford  
Biotechnology Patent Examiner  
October 6, 2005



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